

INOGEN™ EL (Extended Longevity) ICD

Models D140, D141, D142, and D143

- Designed to be the world's longest lasting ICD.
- Powered by **ENDURALIFE™** Battery Technology which enables the longest projected longevity, backed by four independent studies¹⁻⁴ and over six years of real-world data.⁵
- The world's thinnest ICD designed to enhance patient comfort.⁶
- Includes the new EasyView™ header with color coded lead ports, designed to improve implant efficiency.
- Offers an uncompromised set of features including:
 - An advanced system solution for patient comorbidities and HF monitoring (HF Perspectiv™ Report, LATITUDE™ NXT Remote Patient Management enabled with weight scale and blood pressure sensors, and Respiratory Rate Trend).
 - AcuShock™ Advanced Technology, multiple programmable options to reduce inappropriate and unnecessary shocks, including a choice of rhythm discriminators, antitachycardia pacing (ATP) therapy in all rates zones, and advanced sensing and filtering.
 - AV Search+ and Rhythmiq™ give clinicians options to appropriately manage RV pacing in patients with varying degrees of conduction block.
 - Safety Core™ technology is intended to provide lifesaving shock therapy and basic pacing functionality in the event of an unrecoverable fault.



Mechanical Specifications and Reimbursement Information

| Model | Type | Size (cm) (W x H x D) | Mass (g) | Volume (cc) | Connector Type (RA RV LV) | C-Code |
|-------------|------|--------------------------|-------------|----------------|------------------------------|--------|
| D140 | VR | 5.37 x 7.36 x 0.99 | 68.9 | 29.5 | RV:DF4 | C1722 |
| D141 | VR | 5.37 x 7.79 x 0.99 | 70.7 | 31.5 | RV:IS-1/DF-1 | C1722 |
| D142 | DR | 5.37 x 7.68 x 0.99 | 71.4 | 31.0 | RA:IS-1;RV:DF4 | C1721 |
| D143 | DR | 5.37 x 7.79 x 0.99 | 71.0 | 31.5 | RA:IS-1;RV:IS-1/DF-1 | C1721 |

Pulse Generator Projected Longevity (All Models ^{a,b,c,d})

| Pacing | Longevity (years) at 500Ω, 700Ω, and 900Ω Pacing Impedance (RV) | | | | | |
|--------|---|------|------|------|------|------|
| | 500Ω | | 700Ω | | 900Ω | |
| | VR | DR | VR | DR | VR | DR |
| 0% | 11.7 | 11.2 | 11.7 | 11.2 | 11.7 | 11.2 |
| 15% | 11.5 | 10.8 | 11.5 | 10.9 | 11.6 | 10.9 |
| 50% | 11.0 | 10.0 | 11.1 | 10.1 | 11.2 | 10.2 |
| 100% | 10.3 | 9.0 | 10.6 | 9.2 | 10.8 | 9.3 |

a Assumes Zip™ telemetry use for 1 hour at implant time and for 40 minutes annually for in-clinic follow-up checks.

b Assumes standard use of the LATITUDE Communicator as follows: Daily Device Check on, monthly Full Interrogations (scheduled remote follow ups, and quarterly patient-interrogations).

c Assumes 60 min⁻¹ LRL, ventricular and atrial settings of 2.5 V pacing pulse Amplitude and 0.4 ms pacing pulse width; RA Impedance 500Ω; sensors On.

d Projected longevity is calculated assuming 3 maximum energy charging cycles per year, including automatic capacitor re-forms and therapeutic shocks. For the final year of device service, an additional 5 charging cycles are assumed to account for additional automatic capacitor re-forms as the device approaches the Explant indicator. These calculations also assume 3-channel EGM Onset is set to On, and that the pulse generator spends 6 months in Storage mode during shipping and storage.

Additional Longevity Information

- For longevity calculations based on different settings please contact Boston Scientific technical services or your local representative.
- Boston Scientific devices have corporate warranties at 10 years (VR) and 8 years (DR). See BostonScientific.com/warranty for complete warranty terms and conditions.
- Devices use Li/MnO₂ chemistry.
- The Usable Battery Capacity is 1.9 Amp-hours for the EL ICD (typical implant to battery capacity depleted).
- Shelf life is 2 years (before use by).

Longevity projections as provided in the product labeling. Specific programmable parameter ranges available in product labeling. Product labeling available at BostonScientific.com/ifu.

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Pacing Therapy

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| Brady Modes | Normal: DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off Temporary: DDD, DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off |
| AT/AF Management | ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), PMT Termination. Rate Smoothing |
| Rate Adaptive Pacing | Accelerometer with sensor trending function |
| RV Pacing Reduction | AV Search+, Rhythmiq™, AV Delays to 400 ms, Rate Hysteresis |

Patient Diagnostics

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| Arrhythmia Logbook | Events summary, Stored Electrograms with Annotated Markers, (Intervals and approximately 17 minutes of multi-channel EGM, always with 10 seconds Onset and event storage prioritization). Implant activation of all available EGMs. On screen measurement of all stored signal amplitudes and timing |
| Histograms & Counters | Tachy Events and Brady Counters |
| Daily Trends For Last 365 Days | Events, Activity Level, Atrial Burden, Respiratory Rate, Heart Rate, Lead impedances and amplitudes <i>To note: Automatic activation of all available daily trends at implant.</i> |
| AT/AF Diagnostics | % Atrial Burden, Daily burden, Average V-rate during ATR Mode Switch Episode |
| Heart Failure Therapy/ Diagnostics | HF Perspectiv™ report, Respiratory Rate Trend, Weight, Blood Pressure, Heart Rates, Atrial Arrhythmia Burden, Activity Level, A & V Arrhythmias, Pacing Histograms <i>To note: Weight and Blood Pressure are only available via LATITUDE.</i> |

Device Testing/Induction Methods

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| Induction Methods | Vfib Induction, Shock on T Induction, Programmed Electrical Stimulation (PES), 50 Hz/Manual Burst Pacing |
| Commanded Therapy Methods | Commanded Shock, Commanded ATP |

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1. Alam M, Munir B, Rattan R, Flanagan S, Adelstein E, Jan S, Saba S. Battery Longevity in Cardiac Resynchronization Therapy Defibrillators. 2013; Europace (2013) doi: 10.1093/europace/eut301. First published online: October 6, 2013.
2. J. Hjortshøj S, Johansen J, Jorgensen O, Nielsen J, Petersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry. Presented at HRS 2014.
3. Ellis C, Markus T, Dickerman D, Orton J, Hassan S, Good E, Okabe T, Greenspon A. Ampere Hour as a Predictor of CRT ICD Pulse Generator Longevity: A Multi-Center Study. Presented at HFSA 2014. [http://www.onlinejcf.com/article/S1071-9164\(14\)00337-6/fulltext](http://www.onlinejcf.com/article/S1071-9164(14)00337-6/fulltext).
4. J. Williams, R. Stevenson. Contemporary Cardiac Resynchronization Implantable Cardioverter Defibrillator Battery Longevity in a Community Hospital Heart Failure Cohort. Presented at HFSA 2014. HYPERLINK "[http://www.onlinejcf.com/article/S1071-9164\(14\)00389-3/fulltext](http://www.onlinejcf.com/article/S1071-9164(14)00389-3/fulltext)"
5. Boston Scientific CRM Product Performance Report, Data on file.
6. Competitive comparisons: PHYSICIAN'S TECHNICAL MANUAL DYNAGEN™ EL ICD, DYNAGEN™ MINI ICD, INOGEN™ EL ICD, INOGEN™ MINI ICD, ORIGEN™ EL ICD, ORIGEN™ MINI ICD 2014 page 27-29. PUNCTUA™ ICD, ENERGEN™ ICD, INCEPTA™ ICD -PHYSICIAN'S TECHNICAL MANUAL 2012 page 40-41. PROTECTA™ XT VR D314VRM 2013 page 330. EVERA™ XT VR DVBB1D4 2013 page 24. AnalyST™, AnalyST Accel™, Current Accel™, Fortify™, Fortify™ ST, Promote™, Promote Accel™, Promote™ Q, Unify™ Devices User's Manual 2013 page 29. St. Jude Medical™ High-Voltage Devices User's Manual 2013 page 16. Ileo 7 Family of ICDs and CRT-Ds Technical Manual 2013 page 217.

ICD Systems from Boston Scientific – DYNAGEN™ EL ICD, DYNAGEN™ MINI ICD, INOGEN™ EL ICD, INOGEN™ MINI ICD, ORIGEN™ EL ICD, ORIGEN™ MINI ICD

Indications and Use: Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications: Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

Warnings: Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias.)

Precautions: For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information.

Potential Adverse Effects: Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.

(Rev. A)

Tachyarrhythmia Therapy

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| Sensing/Detection | Zones VF only, or VF and VT or VF, VT, VT-1. Lowest Zone can be Monitor Only |
| Shock Reduction and Appropriate Therapy | AcuShock™ Technology including Onset/Stability™, Rhythm ID™, Dynamic Noise Algorithm (DNA) for sensing, Automatic Gain Control (AGC) with programmable sensing floor, Narrow Band Pass Filter |
| Antitachycardia Pacing Therapy (ATP) Termination | Quick Convert™ in VF Zone. Two programmable ATP schemes in both VT and VT-1 zones. Burst, Ramp, Scan, Ramp-Scan |
| Shock Energy | 41 J stored, 35 J delivered. First two shocks in each zone programmable. VT-1 has 5 shocks, VT has 6 shocks and VF has 8 shocks. Reverse Last Shock Polarity in zone. Programmable RV Coil to RA Coil and Can (TRIAD), RV Coil to Can, RV Coil to RA Coil (COLD CAN) |
| Nominals | VF Zone (200 min ⁻¹)—Detection: Rate and Duration, Therapy: Quick Convert, 8 high energy shocks VT Zone (160 min ⁻¹)—Detection: Rhythm ID or Onset/ Stability, Therapy: ATP x 2, 6 high energy shocks |

Implant/In Clinic Follow Up

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| Implant Communication Mode | Programmable values: Enable use of Zip™ telemetry (MICS) (Requires initial use of wand for device ID) or use wand for all telemetry Nominal: Enable use of Zip telemetry (Requires initial use of wand for device ID) |

Remote Follow Up

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| Patient Triggered Monitor (PTM) | Triggers the storage of two minutes onset and one minute post - EGMs, intervals, and annotated marker data during a symptomatic episode by placing a magnet over the device |
| Beeper Feature (Patient Alerts) | Beep During Capacitor Charge, Beep when Explant is Indicated, Beep when Lead Impedance measurement (Shock or Pace) is Out-of-Range |
| Magnet Feature | Magnet Response (Off, Store EGM, Inhibit Therapy) |
| Remote Monitoring | This device is LATITUDE™ enabled |
| Wireless | Remote follow-up for all devices (MICS) |

Boston Scientific
Advancing science for life™

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